

REMARKS**CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH****A. POSSESSION OF THE CLAIMED INVENTION**

The Examiner maintained the rejections of claims 61-82 under 35 U.S.C. § 112, first paragraph because the specification allegedly did not describe the invention sufficient to demonstrate that the inventors had possession of the claimed invention. The Applicants respectfully traverse the present rejection.

The Examiner maintains the rejection because allegedly there is an "absence of a definition in the instant specification of the term accessory molecule, and given the divergent structures and functions of the accessory molecules disclosed (costimulatory molecules, adhesion molecules and survival molecules), the genus of said accessory molecules that would be effective in the recited method ... would not be readily apparent to one of skill in the art, without further guidance from [sic] the specification".

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48

USPQ2d 1641, 1647 (1998).

The Examiner's assertion that there is an "absence of a definition ... of the term accessory molecule" is without merit. The specification discloses that accessory molecules include, "costimulatory molecules, adhesion molecules, and survival molecules, [and] are effective in concert with the MHC class II heterodimer complexed with peptide in activating CD4⁺ cells...". See, e.g., page 21, lines 4-9. The specification further provides specific examples of each type of accessory molecule (see below). Thus, the meaning of "accessory molecule" in the context of the invention is disclosed in the specification.

The Examiner's assertion that, "the genus of said accessory molecules...would not be readily apparent to one of skill in the art" is also without merit. As mentioned above, the accessory molecules of the present invention are, "effective in concert with the MHC class II heterodimer" in activating CD4⁺ cells. The accessory molecules were well known to one skilled in the art at the time the present application was filed. See, e.g., Mondino et al. (1994) Leukocyte Biology 55:805-815. Furthermore, the specification discloses specific examples of useful accessory molecules including: costimulatory molecules such as B7.1 and B7.2, adhesion molecules such as intercellular cell adhesion molecule-1 (ICAM-1) and lymphocyte function-associated antigen-3 (LFA-3), and survival molecules such as Fas ligand (FasL) and CD70. See, e.g., page 6, lines 19-23; page 21, line 4 through page 24, line 2; and page 72, line 14 through page 78, line 16 of the specification. Still further, the specification discloses an actual reduction to practice of the present invention. See, e.g., page 83, line 10 through page 87, line 21 including the results displayed in Table 1 on page 84. Based upon the disclosures in the specification, the knowledge available in the art, and the reduction to practice of the present invention; one skilled in the art can reasonably conclude that the inventors were in

possession of the claimed invention at the time the invention was filed. The Examiner has failed to make a *prima facie* case that the inventors did not have possession of the claimed invention because the genus of accessory molecule is disclosed in terms of function and with numerous examples expressly recited, as discussed herein above. The Applicants respectfully request that the present rejection be withdrawn.

B. ENABLEMENT

The Examiner maintained the rejection of claims 61-82 under 35 U.S.C. § 112, first paragraph because the specification allegedly, "does not reasonably provide enablement for said method comprising any cell, nor any accessory molecule".

Claims 61-82 do not recite "any cell". The method of claims 61-81 is directed to producing a eukaryotic poikilothermic synthetic antigen presenting cell. Accordingly, the specification is not required to enable "any cell" because the claims do not recite "any cell".

The Examiner further alleges that, "the specification does not disclose that said advantages are transferable to a cell line from any eucaryotic poikilothermic organism". To the contrary, the specification discloses, for example, at page 8, lines 4-13 that eukaryotic poikilothermic cell lines are preferred cells for use in the claimed method. The specification further discloses a working example of the claimed method in *drosophila* cells which are eukaryotic poikilothermic cells. Thus, the specification asserts and demonstrates enablement of the claimed method in eucaryotic poikilothermic cells.

Referring to accessory molecules, the Examiner asserts that the specification lacks a definition of accessory molecules. The present assertion is without merit as discussed above in the "Possession of the Claimed Invention" section.

Still referring to accessory molecules, the Examiner further

asserts that the "broad scope of the accessory molecules known and unknown encompassed by the instant claims...would require undue experimentation to predict the success of the recited method...". "Known" accessory molecules are asserted in the specification to be useful in the present method. This is not disputed with any reasoning to the contrary by the Examiner. Furthermore, the record shows that the claimed method is enabled in regard to "known" accessory molecules including B71.1, B71.2, ICAM-1, ICAM-2, ICAM-3, FasL, CD70, and LFA. With regard to "unknown" accessory molecules, the claims do not recite "unknown accessory molecules"; thus, the specification is not required to enable "unknown accessory molecules".

Still referring to accessory molecules, the Examiner's assertion that there is a lack of specific guidance regarding accessory molecule function in eucaryotic poikilothermic cells such that the claimed method would require undue experimentation, is without merit. The preferred use of eucaryotic poikilothermic cells is disclosed, for example, at page 8, lines 4-31 of the specification. The specification further discloses that accessory molecules are effective in concert with the MHC class II heterodimer complexed with peptide in activating CD4⁺ cells...". See, e.g., page 21, lines 4-9. The specification also discloses working examples of the claimed invention using a variety of accessory molecules, for example, at page 83, line 10 through page 87, line 21 including the results displayed in Table 1 on page 84.

The claimed invention is enabled because one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. The claims are enabled over their entire scope because eucaryotic poikilothermic cells are disclosed as preferred for use in the claimed method, the meaning of accessory molecule is well known in the art and defined in the

specification to include an activator of CD4+ cells (with MHC class II heterodimer), and working examples (although not required) of the claimed method are disclosed in the specification providing detailed guidance for practicing the claimed invention.

CONCLUSION

The Applicant respectfully requests that the Examiner enter the present response herein, withdraw all claim rejections, and place the claims in condition for allowance.

The Examiner is requested to contact the representative for the Applicants, to discuss any questions or for clarification. If there are any further fees associated with this response, the Director is authorized to charge our Deposit Account No. 19-0962.

Respectfully submitted,

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Date


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